

### REMARKS

The above RCE has been presented to correct errors in claims 34-36 identified in preparing for an appeal. Claims 34-36 have been amended to define a structure consistent with example 111. Other minor errors have been also corrected.

Claims 1-5, 9, 10, 12, 14-18, 20-22, 24-30, 34-37, 39, 40, 42, 45-49 are pending in this application and are rejected under 35 USC §112, first paragraph, for allegedly not satisfying the written description requirement and for not being enabled by the disclosure.

Applicants maintain that there is written description for the aryl ureas claimed. The scope of the compounds claimed is broad, but this scope is finite and discernable to one skilled in the art. The compounds claimed are diaryl ureas which have prescribed structures bound directly to the urea group. The substituents on these structures can vary widely and are broadly defined. They are limited in size and composition and when considering the large number of substituent groups described as preferred, one skilled in the art would clearly recognize the chemical bonds and configurations for the atoms within these moieties are conventional and well known in the art. While every substituent within the scope of this language has not been identified, such a description is not necessary. The definition provides enough information to determine whether a substituent falls within its scope. The examiner has not provided one example wherein such a determination would be difficult or provide an ambiguous result.

The specification also clearly provides an enabling disclosure for the aryl ureas claimed, the pharmaceutical compositions that contain them and the treatment methods that use them for the reasons stated in the previous reply. The enablement requirement is satisfied if, given what those of ordinary skill in the art already know, the specification teaches those in the art enough that they can make and use the claimed invention without undue experimentation. See *Amgen v Hoechst Marion Roussel*, 314 F.2d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). No evidence has been presented that the disclosure fails to meet the enablement requirement under 35 USC §112, first paragraph, and so the rejection should be withdrawn.

Furthermore, the rejections have been applied to all claims where clearly they do not apply. For example claims 34-36 recite only 9 compounds and do not contain the language objected to. Other claims also do not contain the language objected to. (See claims 2, 16, 17, 34-37, 39, 40, 42, 45-49).

For the reasons indicated above, applicants submit that all pending claims meet the requirements of 35 U.S.C. § 112, first paragraph and that the PTO has failed to meet its burden of establishing that the disclosure does not enable one skilled in the art to make and use the compounds, compositions and methods recited in the claims, such that this rejection should be withdrawn.

#### **Double Patenting**

Applicants maintain the claims herein define compounds which are patentably distinct from those claimed in cited copending applications 10/788029, 10/361,858 and 10/848567.

Copending application 10/788029, is directed to compounds which have a cyano group (-CN) bound to moiety L<sup>1</sup> instead of one the required substituents which appear on the compounds of this invention (-SO<sub>2</sub>R<sub>x</sub>, -C(O)R<sub>x</sub> and -C(NR<sub>y</sub>)R<sub>z</sub>). No evidence has been presented that one skilled in the art would be motivated to replace the substituents which appear on the L<sup>1</sup> moiety with CN or vice versa. In addition, no evidence has been presented that they are equivalent.

Copending application 10/361,858 is directed to compounds which require a pyridine nitrogen be oxidized to an n-oxide. No evidence has been presented that such oxidation would be obvious.

Copending application 10/848567 primarily contains claims directed to the assessment of patients/candidates for a pharmaceutical. There are some method of treatment claims, however in that this application was filed prior to Copending application 10/848567, the rejection for obviousness type double patenting should be withdrawn if the claims are otherwise allowable consistent with MPEP 804 (I)(B).

Relevant portions of MPEP 804 (I)(B) now read as follows:

The "provisional" double patenting rejection should continue

to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in >at least<one of the applications.

#### >Nonstatutory Double Patenting Rejections

If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the other later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.


If “provisional” ODP rejections in two applications are the only rejections remaining in those applications, the examiner should then withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without the need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based on the other two, it is not sufficient to file a terminal disclaimer in only one application addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

Applicants also maintain these rejections are premature and that they are better addressed once allowable subject matter is identified in this application.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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per RJT  
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Attorney Docket No.: BAYER-0015-P03

Date: December 29, 2006